REMARKS

Claims 1, 3-7, 10, and 13-15 are pending in this application. Claims 2 and 9 have been canceled without prejudice. In view of these canceled claims, claims 7, 10, and 13 have been amended to correct their dependencies.

Independent claim 1 has been amended to recite a screening method for prostate cancer in a patient, wherein an increased level of HML-2 retrovirus expression product indicates that the patient should undergo further testing for the presence of prostate cancer. Support is found in the specification, for example, at page 25, lines 21-25.

Independent claim 1 has also been amended to recite that the expression product is an RNA, or its encoded polypeptide, corresponding to the gag or pol domain of the retrovirus. A description of nucleotide sequences corresponding to the gag and pol domains of HML-2 retroviruses is found, for example, at page 76, line 28 to page 78, line 29, and Figure 6.

Accordingly, no new matter is added.

The Rejections under 35 U.S.C. § 112, ¶ 1 (Written Description)

Claims 1-7, 9, 10, and 13-15 stand rejected as not sufficiently described under 35 U.S.C. § 112 ¶ 1. Applicants respectfully traverse this rejection insofar as it applies to independent claim 1, and its pending dependent claims 3-7, 10, and 13-15, as now amended.

The written description requirement for a claimed genus may be satisfied through description of a representative number of species. These representative species may be described by actual reduction to practice, by disclosure of functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicants were in possession of the claimed genus.

Regents of Univ. of Cal. v. Eli Lilly, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Amended claims 1, 3-7, 10, and 13-15 meet this standard. Applicants have described a representative number of species of the genus claimed, through actual reduction to practice and also through disclosure of functional characteristics with a correlation between function and structure.

Independent claim 1 recites a method of screening for prostate cancer. The method comprises assaying a level of an HML-2 retrovirus encoded expression product in a patient prostate or blood sample, wherein an increased level relative to a control sample level indicates that the patient should undergo further testing. To advance prosecution, claim 1 has been amended to recite that the expression product is within a well-defined genus, namely "an RNA corresponding to the gag or pol domain of the [HML-2] retrovirus, or a polypeptide encoded by said RNA."

Applicants have described 16 RNA expression products that were significantly up-regulated in prostate tumor probes, relative to normal probes. See page 75, line 26 to page 76, line 26 and Table 6. All of these expression products are representative species within the recited genus of "an RNA corresponding to the gag or pol domain of the [HML-2] retrovirus . . . " The sequences of these expression products are provided. See page 77, lines 13-14. Thus, representative species of the claimed genus are described by actual reduction to practice.

Also, the consensus sequences for those expression products corresponding to (1) the HML-2 gag domain (SEQ ID NO: 11), (2) the HML-2 5′ pol region (SEQ ID NO: 12), and (3) the HML-2 3′ pol region (SEQ ID NO: 13) are indicative of a correlation between the structure of these products and their function, as being up-regulated in prostate tumor cells relative to normal cells. See page 77, line 28 to page 78, line 8. The common structure of these expression products is further evidenced by the following:

(1) the HML-2 gag domain expression products had 87-99% and 79% homology to the HERV-K(II) and HERV-K10 gag regions, respectively;

(2) the HML-2 5′ pol domain expression products had 87-97% and 81-89% homology to the HERV-K(II) and HERV-K10 5′ pol regions, respectively; and

(3) the HML-2 3′ pol domain expression products had about 89% homology to the HERV-K(II) and HERV-K(10) 3′ pol regions, respectively,

See page 78, lines 9-17 and Table 5 28 to page 78, line 29, and Figure 5.

Moreover, the specification provides numerous additional representative sequences falling within the claimed genus of "an RNA corresponding to the gag or pol domain of the [HML-2] retrovirus, or a polypeptide encoded by said RNA." Additional gag nucleotide sequences are described on page 16, lines 7-9. Also, gag polypeptide sequences are described on page 16, lines 10-12, with the alignment of these gag polypeptide sequences and their consensus sequence described in Figure 7. Additional pol nucleotide sequences are described on page 16, lines 24-25. Also, pol polypeptide sequences are described on page 16, lines 27-28, with the alignment of these pol polypeptide sequences and their consensus sequence described in Figure 8.

Applicants respectfully submit that the specification describes a representative number of species within the well-defined, claimed genus of "an RNA corresponding to the gag or pol domain of the [HML-2] retrovirus, or a polypeptide encoded by said RNA." In particular, the species are described in terms of actual reduction to practice, where species within the claimed genus were shown to be up-regulated in prostate tumor cells. High levels of homology among these species demonstrate their closely related structures. Additional individual species are also described and aligned to show their consensus sequences. The invention of amended claims 1, 3-7, 10, and 13-15 is therefore more than sufficiently described, such that one skilled in the art could reasonably conclude that Applicants had possession of this invention. *Moba, B.V. v.*

Diamond Automation, Inc., 325 F.3d 1306 (Fed. Cir. 2003) and *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991).

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, ¶ 1 for lack of written description are respectfully requested.

The Rejections under 35 U.S.C. § 112, ¶ 1 (Enablement)

Claims 1-7, 9, 10, and 13-15 stand rejected as lacking enablement under 35 U.S.C. § 112 ¶ 1. Applicants respectfully traverse this rejection insofar as it applies to independent claim 1, and its pending dependent claims 3-7, 10, and 13-15, as now amended.

To satisfy enablement, the Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Amended claims 1, 3-7, 10, and 13-15 meet this standard.

To advance prosecution, independent claim 1 has been amended to recite a method of screening for prostate cancer. The method comprises assaying a level of an HML-2 retrovirus encoded expression product in a patient prostate or blood sample, wherein an increased level relative to a control sample level indicates that the patient should undergo further testing. The amendments therefore clarify that the claimed method does not require a definitive diagnosis of cancer. The Office Action's insistence on complete certainty with respect to all HML-2 expression products and all tumor samples (see pages 4 and 5), is therefore misplaced.

The claimed invention is practiced by assaying a level of an HML-2 gag or pol domain expression product as a basis for screening a patient to determine whether further testing is warranted. Applicants respectfully submit that the specification more than adequately apprises

those skilled in the art how to make and use the full scope of the claimed invention.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, ¶ 1 for lack of enablement are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, all pending claims of this application are believed to be in condition for allowance. A written indication of the same is respectfully requested. This response is believed to completely address all of the substantive issues raised in the final Office Action mailed August 23, 2006.

Please continue to direct all correspondence in this application to Novaris Inc. (formerly Chiron Corporation), Intellectual Property Dept., R440, 4560 Horton Street, Emeryville, CA 94608-2916.

Respectfully submitted,
BANNER & WITCOFF, LTD.

Date: December 26, 2006

By: Benjamin C. Spehlmann
Benjamin C. Spehlmann
Reg. No. 45,649
By: William J. Fisher
Reg. No. 32,133

Customer No. 22907